JUL 2 4 2000

SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

BONUS ENTERPRISES CORPORATION'S MECHANICAL WHEELCHAIRS

K001391
p. 1 of 2

1. **ESTABLISHMENT NAME & ADDRESS:**
   BONUS ENTERPRISES CORPORATION
   228 LAKE MERCED HILL,
   SAN FRANCISCO, CA, 94132
   Tel: 877-722-6687; Fax: 650-994-5333

2. **REGISTRATION NUMBER:** 2954308.

3. **OFFICIAL CONTACT PERSON:** Jeff Tepermeyster, COO

4. **MANUFACTURER:**
   SHUNDLE A&I INDUSTRIES LTD.
   LIEN TU INDUSTRY PARK,
   LE LIU SHUN DE CITY,
   GUANGDONG, CHINA, 528300
   Tel: (86)-765-563-4271; Fax: (86)-765-563-2146

5. **DEVICE NAME:** Mechanical wheelchairs
   TRADE NAME: "BONUS"

6. **CLASSIFICATION** of the predicate device: IOR
   REGULATORY CLASS: I (GENERAL CONTROLS).
   PANEL CODE: 890.3850

7. **INTENDED USE:** The intended use of the "BONUS" mechanical wheelchairs is to provide mobility to persons limited to a sitting position.

8. **DEVICE DESCRIPTION:** "BONUS" mechanical wheelchairs are manually operated, self propelled devices. They may also be used as an attendant propelled patient transport device in hospitals, nursing homes, extended care facilities, etc.

The product basically consists of the following main components: frame, large rear wheels with hand rims, smaller front swivel wheels for steering/turning, armrests, foot rests and seating surface. Strong, flame retardant upholstery is used for such seating surfaces.

The wheelchair frame is constructed from round metal tubing; side frames are of welded construction and are secured to other frame members using screws and bolts.

9. **PERFORMANCE STANDARDS:** "BONUS" mechanical wheelchairs meet the applicable performance standards specified in the internationally recognized quality requirements of ISO 9002.

10. EQUIVALENT DEVICES:

1. "Bantex" mechanical wheelchairs
2. "Everest & Jennings" mechanical wheelchairs

11. SUBSTANTIAL EQUIVALENCE:

Each of the products is manually operated, user or attendant propelled, mechanical wheelchair with the same intended function and use which is to provide mobility to persons that may be limited to a seated position.

Bonus Enterprises Corporation's mechanical wheelchairs are also substantially equivalent to numerous mechanical wheelchairs currently on the market, for which FDA has granted marketing clearance through the 510(k) premarket notification process.

More specifically, "Bonus" mechanical wheelchairs are substantially equivalent to both "Bantex" (K915262; 01/13/1992) and "Everest & Jennings" (K930413; 03/31/1993) mechanical wheelchairs in terms of basic design, features and/or intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 2 4 2000

Mr. Jeff Tepermeyster
Bonus Enterprises Corporation
228 Lake Merced Hill
San Francisco, California 94132

Re: K001391
Trade Name: "Bonus" Mechanical Wheelchair
Regulatory Class: II
Product Code: IOR
Dated: April 28, 2000
Received: May 2, 2000

Dear Mr. Tepermeyster:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) NUMBER (IF KNOWN): K001391

DEVICE NAME: "BONUS" MECHANICAL WHEECHAIRS

INDICATION FOR USE:

Provide mobility to persons physically challenged and limited to sitting positions

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off)
Division of General Restorative Devices
510(k) Number K001391

Prescription use_____ OR Over-The-Counter Use X
(Per 21 CFR 801.109) (Optional Format 1-2-96)